

PATENT  
670001-2002.4  
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### REMARKS

Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

#### **I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1-33 are now pending. Claims 30-33 have been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims, as originally presented and presented herein, are in full compliance with the requirements of 35 U.S.C. 112. The newly presented claims and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112, rather the claims were added solely to present a set of claims directed towards the elected subject matter, as requested in the March 12, 2003 Office Action.

The March 12, 2003 Office Action required amendment of claims 26-29 to encompass only the subject matter elected by Applicants. However, as Applicants have made the current election with traverse, claims 26-29 are not amended at this time. New claims have been added to encompass only that subject matter of claims 26-29 that is presently elected. Should the Examiner make the restriction requirement final, claims 26-29 may be cancelled along with the remaining claims of the non-elected groups, e.g., upon an indication of allowable subject matter.

#### **II. RESPONSE TO THE RESTRICTION REQUIREMENT**

The March 12, 2003 Office Action called for restriction from among the following:

- Group I: Claims 1-6, 9-11, 26, 28, drawn to polypeptide, classified in class 424, subclass 248.1;
- Group II: Claims 7, 22, 29, drawn to a method of diagnosis using polypeptide, classified in class 435, subclass 7.1;
- Group III: Claims 8, 23, 27, drawn to method of immunization using polypeptide, classified in class 424, subclass 9.1;
- Group IV: Claims 12-20, 26, 28, drawn to DNA, vector, and transformed cell, classified in class 536, subclass 23.7;
- Group V: Claim 21, drawn to a method of using DNA, vector, and transformed cell, classified in class 536, subclass 23.7;

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- Group VI: Claim 29, drawn to method of diagnosis using DNA, classified in class 536, subclass 24.32;
- Group VII: Claim 27, drawn to method of immunization using DNA, classified in class 514, subclass 44;
- Group VIII: Claims 24, 25, drawn to antibody, classified in class 424, subclass 139.1;
- Group IX: Claim 29, drawn to method of diagnosis using antibody, classified in class 424, subclass 7.1.

Group I is elected, with traverse. And, as new claims 30 and 32 are similar to claims 26 and 28, it is respectfully submitted that should the Restriction Requirement stand, claims 26 and 28 should be added to Group I, such that applicants elect, with traverse, the claims of Group I, namely, claims 1-6, 9-11, 26, 28, 30 and 32.

Similarly, claims 31 and 33 are similar to claims 27 and 29, respectively, such that it is respectfully requested that claim 31 be joined to Group III, and claim 33 be joined to Group II.

As previously stated, should the Restriction Requirement be made final, claims 26 and 28 may be cancelled, along with the remaining non-elected claims.

The claims of the present invention, as grouped in Groups I-IX, all relate to polypeptides, the nucleic acids encoding such polypeptides, and methods and compositions using the same for immunizing animals.

The Office Action states that the "inventions are distinct ... because ... Inventions I and IV-IX are drawn to structurally and functionally distinct molecules." Office Action 3. The claims of Group I are drawn to polypeptides, whereas the claims of Groups IV-VII are drawn to nucleic acids which encode the polypeptides of Group I. Consequently, there is a relationship between the claims of Groups I and IV-VII which would make any search and examination co-extensive.

It is further stated that Groups I and II are related as product and process of use, and that as the polypeptides of Group I may be used in a materially different process (*i.e.* immunization against infection with mycobacteria), the Groups are distinct. Again it is pointed out that any search of these Groups would likely be co-extensive.

Groups I and III are also considered related as product and process of use, and it is stated that because the polypeptide of Group I may be used for *in vitro* diagnosis of infection with

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mycobacteria, the groups are distinct. Again, it is pointed out that any search of these Groups would likely be co-extensive.

Groups II and IV-IX are also allegedly distinct as being "drawn to structurally and functionally distinct molecules." Office Action at 4. The same reasoning is used to distinguish between Groups III and IV-IX; IV and VIII-IX; V and VIII-IX; VI and VIII-IX; and Groups VII and VII-IX. As stated previously, there is a relationship between the claims of all the Groups which would make any search and examination co-extensive. Furthermore, there has been no showing that such a search would be a serious burden on the Examiner.

The Office Action also states that Groups II and III are drawn to patentably distinct methods which use different steps and have different results. Allegedly, the same distinction may be made between Groups V and VI, V and VII, and Groups VI and VII. Again, the search of these groups would likely be co-extensive, and there has been showing that such a search would be a serious burden on the Examiner.

Furthermore, the Office Action states that Groups IV and V are related as product and process of use, and that the DNA, vector and transformed cells of Invention IV can be used to immunize hosts against infection with mycobacteria, rendering the Groups distinct. Similar statements are made to distinguish Groups IV and VI, IV and VII, and VIII and IX. In each case, it is alleged that the Groups are related as product and process of use, and that product may be used in a materially different process. Again, it is pointed out that any search of these Groups would likely be co-extensive, and, no showing has been made that such a search would be a serious burden on the Examiner.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions." *Id.*

It is respectfully submitted that the claims of the present application, Groups I-IX, should be searched and examined together. As stated above, searching the claims of Groups I-IX would likely be co-extensive since the claims of Groups I-IX all relate to polypeptides, the nucleic acids encoding such polypeptides, and methods and compositions using the same for immunizing

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animals. Furthermore, no showing has been made that searching all of the claims would be an undue burden on the Examiner, rendering the requirement for restriction improper. Therefore, for this reason alone restriction should be withdrawn.

Moreover, in accordance with MPEP 821.04 and the February 28, 1996 "Guideline on Treatment of Product and Process Claims...", 1184 TMOG 86 (March 26, 1996), the claims of Group II are subject to rejoinder with the claims of Group I, as are the claims of Group III. Accordingly, Groups I -III should be searched and examined in the same application.

Additionally, the Examiner's attention is respectfully drawn to MPEP §808.02 which states, "even with patently distinct inventions, restriction is not (emphasis added) required unless one of the following reasons appears:

Separate classification;  
Separate status in the art; or  
Different field of search[.]"

Indeed, Groups I, III, V, VIII and IX are all classified in class 424. Therefore, at the least, the claims of Groups I, III, V, VIII and IX should be rejoined on the basis of classification; and, again, at the very least on the basis of the "Guideline on Treatment of Product and Process Claims...", Groups I-III should be rejoined into one Group and searched and examined in this application.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the search and examination of each Group would be likely to be co-extensive, especially as there unity of invention among the Groups and Groups are subject to rejoinder, and Groups share common classification, and, in any event, search and examination of the Groups would involve such interrelated art that the search and examination of the entire application can be made without undue or serious burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

Thus, it is initially respectfully requested that the restriction requirement be reconsidered and withdrawn in its entirety.

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Alternatively, it is respectfully requested that at the very least there be rejoinder of Groups, e.g., reformulation of the restriction requirement such that the subject matter of Groups I-III are rejoined and searched and examined in this application.

### CONCLUSION

In view of the amendments and remarks herein, reconsideration and withdrawal of the restriction requirement, or at the very least its reformulation, are requested.

Early and favorable consideration of the application on the merits, and early Allowance of the application are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP  
Attorney for Applicants

By: 

Thomas J. Kowaleki

Reg. No. 32,147

Angela M. Nigro

Reg. No. 51,107

(212) 588-0800